## REMARKS

In the office action dated May 19, 2004, the Examiner withdrew the allowability of Claims 1-7 and 14-26 in view of U.S. Patent No. 5,964,735 ("Alexander"). Claims 1-4 and 14-26 were rejected under 35 U.S.C. § 102(b) as being anticipated by Alexander or U.S. Patent No. 5,374,250 ("Dixon"). Claims 1-4 and 14-15 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,179,812 ("Botich '812") or U.S. Patent No. 6,123,688 ("Botich '688") or U.S. Patent No. 6,090,077 ("Shaw '077") or U.S. Patent No. 6,015,438 ("Shaw '438") or U.S. Patent No. 6,036,674 ("Caizza et al."). Furthermore, Claims 5 and 6 were rejected under 35 U.S. § 103(a) as being unpatentable over Alexander or Dixon.

The Examiner did not provide any grounds for rejecting Claim 7. Applicants have assumed that this was an oversight, and that the Examiner intended to reject Claim 7 under the same grounds used in rejecting Claims 5 and 6. Therefore, Applicants will address Claim 7 under the assumption that it was rejected under 35 U.S.C. § 103(a) as being unpatentable over Alexander or Dixon.

The May 19, 2004 office action and the references cited therein have been carefully considered. In view of the amendments presented herewith, and based on the following remarks, Applicants believe that the instant application is in condition for allowance.

***Claim Rejections - 35 U.S.C. § 102(b)***

*Claims 1-4, 14-26*

***Alexander and Dixon***

Applicants have amended Claim 1 to recite the following:

1. A method for withdrawing a fluid sample from a patient, comprising the steps of:
   a. providing a sampling device having a housing, a plunger and a needle having a sharpened tip for piercing the patient
   b. collecting fluid from the patient in the housing;
   c. retracting the needle into the plunger so that the sharpened tip of the needle is enclosed within the plunger ~~shielded~~ to prevent inadvertent contact with the sharpened tip; and
   d. expelling the fluid from the housing after the sharpened tip of the needle is retracted into the plunger.

Alexander and Dixon do not teach the steps recited in amended Claim 1. Alexander and Dixon do not teach the step of retracting the needle into the plunger so that the sharpened tip is enclosed within the plunger. In Alexander, a majority of the needle, including the sharpened tip, remains outside of the plunger after retraction (Figs. 3 and 4). In Dixon, a portion of the needle enters the plunger, but the sharpened tip remains outside of the plunger. (Fig. 8C).

Alexander and Dixon also fail to teach the step of expelling fluid after the sharpened tip of the needle is enclosed within the plunger. As stated above, the sharpened needle tips in Alexander and Dixon remain outside of the plunger after the needles are retracted. As a result, Applicants respectfully submit that amended Claim 1 is allowable over Alexander and Dixon.

Claims 2-4 and 14-26 are dependent on amended Claim 1 and incorporate all the features of dependent Claim 1. Therefore, Claims 2-4 and 14-26 are allowable over Alexander and Dixon for at least the same reason that amended Claim 1 is allowable. In addition, Claim 14 recites the steps of biasing the needle rearwardly and releasably retaining the needle against the rearward bias. Claim 15 recites the step of releasing the needle after the step of collecting fluid so that the needle is automatically retracted rearwardly by the biasing element. Claim 16 recites the step of displacing the plunger rearwardly, where the needle is released in response to displacing the plunger rearwardly. Claim 17 recites the step of releasing a needle by manually operating an actuator. As noted above, Alexander and Dixon do not teach a biasing element or automatic needle retraction. Instead, the devices in Alexander and Dixon are manually retractable. Therefore, claims 14-17 recite additional subject matter that is allowable over Alexander and Dixon.

***Claim Rejections - 35 U.S.C. § 102(e)***

*Claims 1-4, 14 and 15*

***Botich '812***

Amended Claim 1 recites a method of withdrawing a fluid sample from a patient, including the steps of retracting the entire needle into a plunger so that the sharpened tip of the needle is completely enclosed within the plunger, and expelling the fluid from the housing after the sharpened tip of the needle is retracted and completely enclosed within the plunger.

None of the cited references teach a method that includes expelling fluid

from the device after the needle is retracted and completely enclosed within a plunger. Botich '812 discloses three types of devices: a syringe (Figs. 1-6), a phlebotomy device (Figs. 7-8) and a catheter insertion device (Figs. 9-13). The syringe has a plunger (24) that may be advanced forwardly to expel fluid out of the device. (Col. 5, lines 31-34). If desired, the plunger can be displaced rearwardly after an injection to draw more fluid into the device. (Col. 5, lines 31-43). The fluid is then expelled by pushing the plunger forwardly in the barrel. At the end of the injection stroke, the plunger may be advanced further in the forward direction to automatically retract the needle into the plunger. In this arrangement, fluid is expelled from the syringe prior to retraction of the needle. Botich '821 does not indicate whether fluid can be drawn into the device after the needle is retracted into the plunger. Assuming fluid can be drawn into the device after the needle is retracted, there is no indication that fluid can be expelled out of the device.

The phlebotomy device (320) in Botich '812 includes a barrel (322) having an open rearward end (322a) for receiving a blood collection container (381), such as a "VACUTAINER", which is a glass tube with a seal at its forward end. The device includes a forward needle (325) for piercing the patient and a rearward needle (384) for piercing the seal on the collection container (381). The phlebotomy device (320) does not include a plunger for expelling fluid from the housing. Further, the phlebotomy device collects fluid in a separable container, not the housing. Further still, the fluid is not expelled from the housing; it is expelled from the container.

The catheter insertion device in Botich '812 (Figs. 9-13) is not described

as a fluid collection device, and there is no indication that the catheter insertion device can operate as a fluid collection device. Based on the foregoing, the subject matter in amended Claim 1 is not taught by any of the devices described in Botich '812.

***Botich '688***

As with Botich '812, Botich '688 fails to teach the step of expelling fluid from a device after the needle is retracted. Instead, Botich '688 teaches a number of retractable needle injectors for injecting medicine from a pre-filled vial of medicine. Assuming the injectors in Botich '688 could act as fluid collection devices, the needles can not be retracted until the end of the injection stroke, after the fluid is expelled. In other words, fluid in the device is expelled before the needle is retracted. Accordingly, amended Claim 1 is believed to be patentable over Botich '688.

***Shaw '077***

Shaw '077 is directed to a retractable needle hypodermic syringe for giving injections. The needle is automatically retracted after the fluid is expelled from the syringe. The syringe includes a plunger with a dislodgeable stopper (42). At the end of the injection stroke, a friction seal around the stopper (42) is broken, allowing the plunger tip to be retracted into the plunger with the needle. This renders the plunger inoperable, so that fluid can no longer be drawn into the device and expelled after needle retraction. In contrast, the claimed method includes the step of expelling the fluid after the needle is retracted. Therefore, amended Claim 1 is patentable over Shaw '077.

***Shaw '438***

Shaw '438 is directed to a retractable needle hypodermic syringe for giving an injection. Shaw '438 discloses a plunger with a dislodgeable stopper (38) that operates similarly to the stopper in the safety syringe disclosed in Shaw '077. The needle is automatically retracted after the fluid is expelled from the syringe, and the stopper is retracted rearwardly with the needle. Therefore, the plunger is rendered inoperable after needle retraction, so that fluid can no longer be drawn into the device and expelled after needle retraction. In contrast, the claimed method includes the step of expelling the fluid after the needle is retracted. Therefore, amended Claim 1 is believed to be patentable over Shaw '438.

***Caizza et al.***

Caizza et al. discloses another retractable needle hypodermic syringe for providing an injection. Like the Shaw references, Caizza et al. does not teach or suggest the step of expelling fluid from a device after the needle is retracted. Specifically, Caizza et al. includes a plunger having a seal that is broken at the end of an injection stroke in order to allow the needle to be retracted into the plunger. Since the plunger seal is broken after the injection, and the needle is then retracted, there is no way to expel fluid from the housing after the needle is retracted, as recited in amended Claim 1. Accordingly, amended Claim 1 is patentable over Caizza et al.

*Claims 2-4, 14 and 15*

Claims 2-4, 14 and 15 are dependent on amended Claim 1 and incorporate all the features recited in amended Claim 1. Therefore, Claims 2-4, 14 and 15 are believed to be allowable over the cited references for at least the same reason that amended Claim 1 is allowable. In addition, Claim 4 recites the

method of Claim 1 wherein the step of retracting comprises the step of displacing the needle rearwardly into the housing while the collected fluid is in the housing. In contrast, the devices in Botich '812, Botich '688, Shaw '077, Shaw '438 and Caizza et al. all retract the needle at the end of the injection stroke, after the collected fluid is expelled from the device. Therefore, Claim 4 recites additional subject matter that is not taught by the cited references.

***Claims Rejections - 35 U.S.C. § 103***

*Claims 5-7*

Claims 5-7 are dependent on amended Claim 1 and incorporate all the elements recited in amended Claim 1, including the steps of providing a device with a biasing element for retracting the needle, retracting the needle so that the sharpened tip is completely enclosed within the plunger, and expelling fluid after the sharpened tip of the needle is enclosed within the plunger. Alexander and Dixon do not teach any of these steps, as discussed earlier. Moreover, there is no evidence that one of ordinary skill in the art could practice these steps when using the devices disclosed in Alexander and Dixon.

In order to practice the steps of method Claims 5-7, one would have to make substantial modifications to the devices taught in Alexander and Dixon. For instance, each device would have to be modified to include a biasing element. There is no indication that a biasing element could be added to the devices in Alexander and Dixon without impairing the operation of the devices. In addition, the plunger in each device would have to be modified so that the plunger can enclose the entire needle, including the sharpened tip of the needle.

Again, there is no evidence that this modification could be done without impairing the operation of the devices.

Assuming that one could modify the plunger in Alexander to enclose the entire needle, there is little motivation to do so. The device in Alexander is designed with a self-destruction feature that renders the needle inoperable so that it cannot be reused. The device is designed to retract the needle into the barrel in a trapped position outside of the plunger, with the needle being trapped between the front end of the barrel and the plunger. This allows the user to advance the plunger forwardly and crumple the retracted needle, preventing the needle from being extended and reused. The self-destruction feature of Alexander would be lost if the entire needle could be retracted and enclosed within the plunger.

Based on the foregoing, persons of ordinary skill in the art would not be motivated to modify the devices of Alexander and Dixon in order to practice the methods of Claims 5-7. Therefore, Claims 5-7 are believed to be allowable over Alexander and Dixon.

***Conclusion***

In light of the foregoing, Applicants believe that this application is in form for allowance. The Examiner is encouraged to contact the Applicants' undersigned attorney if the Examiner believes that issues remain regarding the allowability of this application.

Respectfully submitted,

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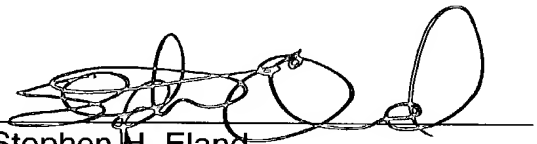
By 
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